

Statement of
James P. Bagian, M.D., P.E
Director, National Center for Patient Safety
and
Jonathan B. Perlin, M.D., Ph.D., M.S.H.A.
Chief Quality and Performance Officer
Veterans Health Administration
Department of Veterans Affairs
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Mr. Chairman and Members of the Committee,

We are pleased to appear before you to discuss VA's ongoing activities and initiatives to ensure the provision of consistent, high quality and safe care to patients. The committee rightly recognizes the link between quality and safety and the fact that quality and safety are fundamental to the work of the VA health care system at all levels. It is important to note that achieving the best possible outcomes for our patients while minimizing safety risks are overarching goals for all elements of the VA system. The Office of Quality and Performance and the National Center for Patient Safety and all other VHA offices have leadership roles and share responsibility for achieving these goals.

For clarity, the fundamental principles, philosophy and basic elements of VA's quality and safety activities are presented separately. However, it is only when all elements work together that the full benefit of each is realized and a number of programs that exemplify this are also discussed.

PATIENT SAFETY

Starting in 1997, VA intensified its already extensive efforts in quality improvement by launching major overt initiatives on patient safety per se (see Attachment 1). By no means were these initiatives the first safety related efforts by VA. For example, prior to 1997 the development and implementation of

clinical guidelines ensured uniform, safe provider performance across all facilities. VA recognized that programs to improve quality and safety in health care often share purposes and corrective actions. However, it believed that patient safety required a new and different approach and set out to create a new culture of safety in which VA employees detect and report unsafe situations and systems as part of their daily work. Studies have shown that this change of culture is a multi-year task. VA is committed to designing and implementing new systems and processes that diminish the chance of error and the elimination of unsafe situations. VA is using a systems approach that emphasizes **prevention -- not punishment** -- as the preferred method to accomplish this goal.

In December 1999, the Institute of Medicine (IOM) released a report “To Err is Human: Building a Safer Health System.” The report’s review of existing studies, which concluded that as many as 98,000 preventable deaths occur each year in United States’ health care due to error, focused national attention on patient safety. The IOM recommended creating a new National Center for Patient Safety (not to be confused with the VA’s own National Center for Patient Safety, which already existed) that would focus on research and policy related to errors in health care, improved error reporting systems, improved analysis/feedback methods, performance standards for health care organizations and individuals, and other specific governmental actions. Importantly, the IOM report cautioned that the focus must be on creating a culture of safety that will require improving systems, not assigning blame.

VA interpreted the IOM report as a validation of its commitment to improving patient safety in its health care system. All of the IOM recommendations applicable to VA have either been in place or were in the process of being implemented prior to the release of the report. While VA has had quality and safety related activities ongoing for many years, it was in 1997 that its formal patient safety program was launched. Leaders in the field of patient safety and medical error outside VA have participated in the design of the system and recognize VA as a pioneer in these efforts.

VA recognized that patient safety is not a VA-specific issue, therefore it asked other health care organizations to join in an effort to understand the issues and to act for patient safety. As a result, the **National Patient Safety Partnership (NPSP)**, a public-private consortium of organizations with a shared interest and commitment to patient safety improvement was formed in 1997. The charter members, in addition to VA, included the American Medical Association (AMA), the American Hospital Association,

the American Nurses Association, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Association of American Medical Colleges, the Institute for Healthcare Improvement (IHI), and the National Patient Safety Foundation at the AMA. Five additional organizations have subsequently joined the charter members in the Partnership: the Department of Defense (DOD) -Health Affairs, National Institute for Occupational Safety and Health, the Food and Drug Administration (FDA), Agency for Healthcare Quality and Research, and the Health Care Financing Administration. This group addresses high impact issues that are of importance to a broad cross section of the health care industry. An example of the Partnership's action and influence was the establishment of an FDA clearinghouse for information related to the effect of Y2K computer issues on medical devices. The NPSP also called public and industry attention to Preventable Adverse Drug Events and promulgated simple actions that patients, providers, purchasers and organizations could take to minimize their chance of an adverse drug event. VA is leading development of an NPSP anthology on issues in patient safety that will serve as a resource for industry, educators, and policy discussion. Also, VA is leading the way in the use of bar-code technology to prevent errors. The NPSP serves as a model of what a private-public collaboration can do to improve patient safety.

VA instituted a **Patient Safety Improvement Awards Program** in 1998 to focus interest on and reward innovations in identifying and fixing system weaknesses. Not only does this produce ideas for patient safety improvements that might otherwise go unnoticed, but it further reinforces the importance that VA places on patient safety activities and involves those at the 'front-line' in a very direct and tangible way.

In 1998, VA created the **National Center for Patient Safety (NCPS)** to lead and integrate the patient safety efforts for VA. This Center was created to lead VA's patient safety efforts and has a direct reporting relationship to the Under Secretary for Health. The NCPS employs human factors engineering and safety system approaches in its activities. The first task for the Center is to devise systems to capture, analyze and fix weaknesses in our systems that affect patient safety.

In 1998 VA formed the **Expert Advisory Panel for Patient Safety System Design** to obtain expert advice to enhance the design of VA's reporting systems.

These experts in the safety field included Dr. Charles Billings, one of the founders of the Aviation Safety Reporting System (ASRS), as well as other experts from NASA and the academic community. They advised us that an ideal reporting system: a) must be non-punitive, voluntary, confidential and de-identified; b) must make extensive use of narratives; c) have interdisciplinary review teams; and d) most importantly, focus on identifying vulnerabilities rather than be a counting exercise. VA has used these principles to design the patient safety reporting systems we have in use or in development. Based on the expert advice and on lessons learned from our mandatory adverse event reporting pilot, the NCPS has developed and rolled out a comprehensive adverse event, close call analysis and corrective action program and computer assisted tool that includes an end-to-end handling of event reports. This system not only allows for the determination of the root causes, but also captures the corrective actions as well as the concurrence and support of local management for implementation. The system includes a number of innovations such as human factors decision support tools and computer aided report tools to determine the root cause of adverse events and close calls.

In 1999, VA established four **Patient Safety Centers of Inquiry**. These Centers conduct research on critical patient safety challenges. Activities at the Centers of Inquiry range from fall prevention and operating room simulators to understanding the role of poor communication in patient safety. The Center in Palo Alto, California, which is affiliated with Stanford University, is a recognized leader in the area of simulation and has been featured prominently in the media. Their simulated operating room allows surgeons and anesthesiologists to train and do research without endangering a patient. VA expects to create additional simulation facilities to train its physicians and other health care professionals. One simulator with appropriate staff could train approximately 600 anesthesiologists and residents per year. This means that virtually all VA anesthesiologists/anesthetists can be trained in a year on clinical situations that could not be simulated safely in actual patients. Another Center at White River Junction, Vermont, is partnering with the Institute for Healthcare Improvement (IHI) to build learning collaboratives aimed at reducing medication errors, a major issue identified in the IOM report. IHI collaboratives will affect several hundred VHA

personnel each year. Other IHI collaboratives have resulted in measurable improvements and similar results are anticipated with medication errors.

In November 1999, the new event and close call reporting system was first pilot tested in VA's VISN 8 (Florida, South Georgia and Puerto Rico). Extensive training and constant mentoring and feedback are provided to assure full understanding of the search for the root cause and redesign of the system. The quality managers, risk managers, and clinicians using the system believe that the new methods analysis of error will make a significant improvement in the care of veterans. Independently, VHA's Patient Safety Improvement Oversight Committee has stated that the reports and corrective actions that are the product of this new approach are superior in numerous ways to the ones from the previous system. By August of this year, all VA hospitals will have received this training and be using this system. To date, there have been nearly 600 participants at these national training sessions. While the vast majority of these participants have been VA employees, we have been pleased to accommodate requests for training about our system from participants in both the public and private sector. Participants have included guests from AHA, Baylor University, DoD, FDA, the Government Accounting Office, Kaiser Permanente, the University of Michigan, the University of Texas, and other private and public health care systems or affiliates. Response from participants has been overwhelmingly positive.

We sought to design reporting systems that would identify adverse events that might be preventable now or in the future. In addition, we sought systems to identify and analyze situations or events that would have resulted in an adverse event if not for either luck or the quick action of a health care provider -- we call such events "close calls." We believe that "close calls" provide the best opportunity to learn and institute preventive strategies, as they will unmask system weaknesses before a patient is injured thus enabling preventive actions to be taken. This emphasis on "close calls" has been employed by organizations outside of health care with great success. It has been said that experience is the best teacher, however it is also the most expensive. In the case of medically related experience that cost can be expressed in terms of tragic consequences. "Close calls" enable us to learn and institute preventive actions without first having to pay the costly tuition born of human tragedy.

To complement our internal system, an agreement to establish the Patient Safety Reporting System (PSRS), a complementary, de-identified voluntary reporting system, was finalized in May of this year with NASA. The PSRS is patterned after the highly successful Aviation Safety Reporting System that NASA operates on behalf of the FAA. It is external to VA and allows all physicians, nurses, pharmacists, laboratory personnel, and others to report unsafe occurrences without fear of administrative or other action being taken against them.

Another key VA strategy to reduce medical errors involves the development of a new curriculum on safety. VA is moving forward with plans to provide education and training relevant to patient safety not only to those already in practice but also at the medical, nursing, and health professional school levels. This will be the first time an extensive safety curriculum will be developed and broadly implemented. VA is particularly well situated to lead the educational effort due to the extensive role it plays in the education of health care professionals in the United States. (VA is affiliated with 105 medical schools and up to one-half of all physicians in the country train in a VA facility during medical school or residency.) Additionally, we have instituted a performance goal to provide VA employees 20 hours of training on patient safety this year.

Based on lessons learned from the review of adverse events, actions are taken at both the local level and nationally. Examples of national level actions are as follows:

- Restricting access to concentrated potassium chloride on patient care units
- Requiring use of barcode technology for patient identification and blood transfusions in operating rooms
- Establishing new procedures for missing patient searches
- Enhancing violent behavior prevention efforts
- Establishing new procedures for verifying water temperature for patient baths/treatments
- Enhanced procedures to ensure safe injection of Radio-Labeled Blood Products
- Enhanced requirements for protective fencing around construction sites

We believe that patient safety can only be achieved by working towards a “culture of safety.” Patient safety improvement requires a new mindset that recognizes that real solutions require an understanding of the “hidden” opportunities behind the more obvious errors. Unfortunately, systems’ thinking is not historically rooted in medicine. On the contrary, the field of medicine has typically ascribed errors to individuals and embraced the name-blame-shame-and-train approach to error reduction. Such an approach by its very nature forecloses the opportunity to find systems solutions to problems. Other industries such as aviation have recognized the failings of this approach and over many years have succeeded in transitioning from a similar blame and fault finding approach to a system-based approach that seeks the root causes of errors to guide them in preventive actions. VA realized how pivotal culture is to improving safety and in 1998 conducted a culture survey of a sample of employees. Of interest, the shame of making an error appeared a more powerful inhibitor of reporting than was fear of punishment. The survey provided information that indicated that employees were intolerant of their own errors and were “ashamed” if others knew that an error had been made. People who have expressed strong feelings of shame are less likely to exchange learning experiences with others, thus thwarting the opportunity for the entire institution to learn from the experience. We plan to survey culture broadly in VA for several years to track the progress of our efforts.

QUALITY MANAGEMENT

Aviation safety has been used metaphorically to describe both opportunities and processes to improve patient safety. It is also an appropriate metaphor for describing the relationship between safety and quality. While much is learned from understanding adverse events and close calls, quality has to be “engineered in.” Safe health systems, like safe aviation, must be designed and implemented to tolerate human imperfection and still achieve reliably good outcomes. Neither quality nor safety can be adequately described independently. While each may receive identifiable and specific support, the overall fabric is far more complex than the individual threads.

VA processes systematically seek to “engineer in” quality. Clinical practice guidelines, electronic medical records, computerized clinical reminders, bar code blood

and medication administration all exemplify systems which are not only designed to reduce the risk for bad outcomes based on human factors, but designed to support achievement of the optimal outcomes possible for patients. All of these initiatives, except practice guidelines, originated outside of the quality and safety offices. VA Research also makes significant contributions to improving quality and safety of patient care (See Attachment 2). All of these efforts and many others represent organizational commitment to quality and safety.

The history of VA's commitment to "engineering in" quality is important. The 1995 publication *Vision for Change* (page 7), described a radical, yet rational, transformation of structure that would support a transformation of culture. The ensuing structural transformation made it possible to embark on a "quality and safety transformation" that is now being realized.

VA articulated its commitment to quality in the broadest sense, and expressly inclusive of safety, in 1996 with the publication of *Prescription for Change*. VA's commitment to quality is galvanized by the Performance Measurement Program operated through the Office of Quality and Performance. The Performance Measurement Program begins with the principle that quality outcomes can, and should, be specified. Through performance contracts, clinicians and managers are accountable for achieving realistic, but ambitious performance targets in defined time frames. A highly evolved measurement program provides ongoing assessment of performance and the data necessary for effective management. Improvement since inception of performance measurement in 1995 is impressive. In many areas where comparative quality data are available, VA meets or exceeds published levels of performance in health care.

VA expressed its commitment to preventive health through development of the Prevention Index. This index supports improvement in evidence-based health services such as immunization, cancer detection, and substance abuse screening. On a 100 point scale, the Prevention Index improved from 33 (1996) to 67 (1997) to 79 (1998) to 81 (1999), a 145% improvement since inception. A parallel 100 point Chronic Disease Index including indicators of care in heart disease, lung disease, diabetes, and hypertension has increased from 45 (1996) to 77 (1997) to 85 (1998) to 89 (1999), a

98% improvement since inception. VA's rates of immunization against pneumonia and influenza now exceed U.S. Public Health Service goals and published private sector performance.

What does this mean in terms of real outcomes for real patients? In the United States, only about 50% of the elderly and patients with chronic disease appropriately receive the recommended pneumonia vaccination. In contrast, in VA, by 1998, the improvement in pneumonia vaccination, from levels consistent with prevailing community rates in 1996, is estimated to have saved almost 4,000 lives in patients with chronic lung disease alone.

These achievements exemplify a critical aspect of the relationship between quality and safety. We may only think of adverse events as the result of an action, be it a preventable error or an unforeseeable and unpreventable consequence. However, adverse outcomes may also be the result of inaction.

VA has approached both under-utilization as well as mis-utilization of appropriate therapy through the development of Clinical Practice Guidelines. The expected outcomes of these guidelines are again supported by performance measures. The myocardial infarction or "heart attack" module of the heart disease guideline endorses the appropriate use of "beta-blocker" medication for eligible patients. While it has been well known for almost a decade that these beta-blockers can significantly reduce the risk of death and rehospitalization, a recent study by Krumholz *et al*/revealed administration of this life-saving therapy to only 51% of 58,000 eligible non-governmental patients. The rate of provision of beta-blockers to patients treated for heart attack in VA hospitals is currently 96%. Improvements in beta-blocker administration from rates already above prevailing community rates in 1995 are estimated to have saved an additional 500 lives.

"Engineering in" quality reduces opportunities for breeches in safety and supports achieving the best possible outcomes. Examples of other formal mechanisms for quality management in VA, which have contributed to objective improvement in the intended health benefits as well as the safety of patients, include the National Surgical Quality Improvement Program, the Continuous Improvement in Cardiac Surgery Program, and the Quality Enhancement Research Initiatives. VA has also established

its leadership in programs for development and implementation of Clinical Practice Guidelines in collaboration with the DoD, and in the area of reliable and efficient electronic physician credentialing through the VetPro initiative of the Federal Credentialing Program.

VA feels strongly that quality can be defined from many perspectives. Admittedly, in this context, technical quality is at issue. However, VA defines six “domains-of-value” which serve as focal points for systematic organizational improvement. Foremost among these is technical quality, and the relationship with safety is incontrovertible. The remaining five domains – access, satisfaction, maximizing functional status, cost-effectiveness, and building healthy communities – are also critical. While all are important to various stakeholders, satisfaction and functional status, in particular, represent outcomes from the Veteran patient’s perspective. As with technical quality, each of these domains is supported by performance measures which link the “vision” for improvement with markers of progress on the journey.

While VA has objectively achieved noteworthy performance successes over the past half decade, we share your concern and empathize with those patients whose care was not representative of the overall progress. We share your outrage when any patient comes to harm, and we recognize that our journey is incomplete. We seek your support in continuing to foster a quality transformation that is the result of the systemization of quality, and that fundamentally embraces the systemization of safety.

CONCLUSION

The National Center for Patient Safety and the Office of Quality and Performance work closely with all elements of VHA to support complementary activities in quality and safety. In the area of quality management, VA’s commitment to linking organizational goals with performance measures has resulted not only in objective improvements in the quality of care, but even achieving some benchmark outcomes. VA has been twice awarded a grade of “A” in managing for results, and will use the performance measurement program and other quality management activities noted to continue to improve quality.

The 2000 Innovations in American Government Awards Program recently selected the National Center for Patient Safety and the Performance Measurement Program as two of 96 semifinalists from among more than 1,300 applicants for this year's awards. Innovations in American Government awards are recognized as one of the most prestigious public service awards in the country. Final selections will be conducted in October.

In the area of patient safety, with no successful models in large health care systems to guide us, VA turned to other high risk, high reliability industries to adopt and adapt principles. We have borrowed both methods and people from safety-conscious settings such as aviation and space travel and from underutilized disciplines like human factors engineering. We have also developed novel approaches and tools where none existed before. These efforts have already produced significant improvements in VA, and we believe will do the same in all health care settings.

We would prefer that all of health care had begun to address the issue of patient safety long ago. For too long, the emphasis has been on holding individuals accountable and hoping that well-intended and well-educated professionals wouldn't make human mistakes, rather than designing systems that don't fail if human errors occur. As the IOM aptly states in the title of its report: "To err is human." We are pleased to be on the leading edge as health care takes a systems approach to patient safety. We are anxious to discover new ways to make VA and all health care safer and improve quality. We appreciate your support of these efforts and intend to keep you fully informed of our progress.